510(k) Summary

FEB 2 1 2014

Applicant/Sponsor:
NovoSource, Inc.
714 East Monument Ave. Suite 220
Dayton, OH, 45402
937-531-6591

Contact Person:
Sharon Kvistad
Navigant Consulting, LLC
9001 Wesleyan Road Suite 200
Indianapolis, IN 46268
317-228-8715
sharon.kvistad@navigant.com

Date of Preparation: February 18, 2014

NAME AND CLASSIFICATION

Proposed Trade Name:	NovoHip Total Hip System
Common Name:	Hip prosthesis
Classification Name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis per 21 CFR 888.3358 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis per 21 CFR 888.3353
Device Product Code:	LPH, LZO
Predicate Devices:	Stelkast Provident Hip System (K935484, K033944) Smith & Nephew Biolox Delta Ceramic Femoral Head (K083762) Wright Medical Lineage Acetabular System (K002149)
Device Classification:	Class II

DEVICE DESCRIPTION

The NovoHip Total Hip System is a non-cemented hip prosthesis that consists of a 4-part total hip replacement system including femoral stem, femoral head, acetabular poly liner, and acetabular metal (or shell) components. The femoral head component articulates within the poly acetabular component. The poly acetabular component snaps into the metal acetabular component. The design and sizing of the components correspond to natural hip anatomy to restore normal rotation, extension, and flexion.

The femoral stem component is made from forged Ti 6AL 4V, with a Ti plasma spray coating. The uni-polar femoral head component is made from CoCr, or BIOLOX® delta ceramic, in 28, 32, and 36 mm sizes.

The acetabular poly liner component is made of standard UHMWPE polyethylene in both hooded and non-hooded options. The acetabular poly liner component is offered with different inner and outer diameter combinations to accept various size uni-polar femoral heads and acetabular metal components.

The acetabular metal (or shell) component is made from forged Ti 6AL 4V with a Ti porous coating. It is available in no-hole, cluster-hole, and revision multi-hole styles.

INTENDED USE
Hip joint arthroplasty

INDICATIONS FOR USE
NovoSource hip implant components are indicated for use in cementless reconstruction of the articulating surface of femoral and/or acetabular portions of the hip that are severely disabled and/or very painful as a result of:

- Non-inflammatory degenerative joint disease including osteoarthritis and avascular necrosis
- Rheumatoid arthritis or traumatic arthritis
- Correction of functional deformity
- Non-union femoral neck fracture
- Trochanteric fractures of the proximal femur with head involvement which is unmanageable using other techniques.

The components can be used for primary hip arthroplasty or for revision of a failed total hip arthroplasty.

TECHNOLOGICAL CHARACTERISTICS
The NovoHip Total Hip System has the same intended use as the predicate devices. The NovoHip Total Hip System has similar indications for use as the as the predicate devices. The NovoHip Total Hip System is manufactured from the same materials as the predicate devices. The range of sizes of the NovoHip Total Hip System is similar to the predicate devices.

SUMMARY OF STUDIES

Non-Clinical Testing
The NovoHip Total Hip System underwent the following testing:

- Fatigue Performance Test for NovoHip Stem
- Fatigue Performance Test for the Neck Portion of the NovoHip Stem
- Disassembly Force Test for the NovoHip Neck Taper/Femoral Head Interface
- Range of Motion Test for the NovoHip Total Hip System

- Burst Strength Test for NovoHip Ceramic Femoral Heads (Static Compression)
- Cyclic Fatigue Test for NovoHip Ceramic Femoral Heads (Cyclic Compression)
- Post-Cyclic Fatigue Burst Test for NovoHip Ceramic Femoral Heads (Static Compression)
- Pull-Off Test for NovoHip Ceramic Femoral Heads
- Rotational Stability Test for NovoHip Ceramic Femoral Heads
- Torsional Properties Test for NovoHip Bone Screws
- Driving Torque Test for NovoHip Bone Screws
- Axial Pull-Out Strength Test for NovoHip Bone Screws
- Lever-Out Test for NovoHip Acetabular Shell/Liner Assembly
- Torque-Out Test for NovoHip Acetabular Shell/Liner Assembly
- Push-In Test for NovoHip Acetabular Shell/Liner Assembly
- Push-Out Test for NovoHip Acetabular Shell/Liner Assembly

All devices met the required performance specifications for testing and are considered equivalent to the predicate devices.

Clinical Testing

No clinical testing was required.

CONCLUSION

Based on testing results and the comparisons provided, the NovoHip Total Hip System is considered substantially equivalent to the Stelkast Provident Hip System and the Wright Medical Lineage in material, construction and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 21, 2014

Novosource, Incorporated
% Ms. Sharon Kvistad
Associate Director
Navigant Consulting, LLC
9001 Wesleyan Road, Suite 200
Indianapolis, Indiana 46268

Re: K132158
Trade/Device Name: NovoHip Total Hip System
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: Class II
Product Code: LPH, LZO
Dated: January 13, 2014
Received: January 14, 2014

Dear Ms. Kvistad:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Vincent D Devlin -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132158

Device Name: NovoHip Total Hip System

Indications for Use:

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth FDA Frank -S

Division of Orthopedic Devices